



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT - 7 1999

Ms. Mary E. Helrich, CN
Director of Strategic Planning
FoodScience Corporation
20 New England Drive
Essex Junction, Vermont 05453

Dear Ms. Helrich:

This is in response to your letter of September 29, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that FoodScience Corporation, also dba DaVinci Laboratories of Vermont, is making the following claims, among others, for the products:

DL-Phenylalanine

“A Dietary Supplement to Support Pain Magement [sic] & Proper Mood Balance”

AllerBlend

“Herbal Support When Allergens Are Present.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products, including the name of “AllerBlend,” suggest that they are intended to treat, prevent, or mitigate disease, namely allergies and pain. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-3 10, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 308

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Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-3 10 (BWilliams)

HFD-3 14 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett)

f/t:HFS-456:rjm: 10/6/99:docname:67506.adv:disc41



FoodScience Corporation

DIVISIONS:



FoodScience Laboratories



DaVinci Laboratories

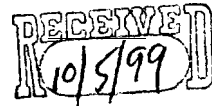
September 29, 1999



UNITED STATES
ANIMAL NUTRITION



VETRI-SCIENCE
LABORATORIES



Food and Drug Administration
Office of Special Nutritionals (HFS-45)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6)(21 U.S.C.343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of **21** CFR 101.93, that FoodScience Corporation, 20 New England Drive, Essex Junction, Vermont 05452 within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

TEXT OF CLAIM:

"Herbal Support When Allergens Are Present"

NAME OF PRODUCT(s): FoodScience of Vermont **"AllerBlend"** and
DaVinci Laboratories of Vermont **"AllerBlend"**

The undersigned certifies that the information contained in this notice is complete and accurate and that FoodScience Corporation has substantiation that the statement is truthful and not misleading.

Sincerely,

Mary E. Helrich, CN

Director of Strategic Planning

MEH:chg

67506



FoodScience Corporation

DIVISIONS:



FoodScience Laboratories



DaVinci Laboratories

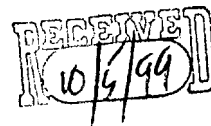


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Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6)(21 U.S.C.343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that FoodScience Corporation, 20 New England Drive, Essex Junction, Vermont 05452 within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

TEXT OF CLAIM:

"A Dietary Supplement to Support Pain Magement & Proper Mood Balance"

NAME OF PRODUCT(s): FoodScience of Vermont **"DL-Phenylalanine"** and
DaVinci Laboratories of Vermont **"DL-Phenylalanine"**

The undersigned certifies that the information contained in this **notice is complete** and accurate and that FoodScience Corporation has substantiation that the statement is truthful and not misleading.

Sincerely,

Mary E. Helrich, CN
Director of Strategic Planning

MEH:chg

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